Comparative effectiveness—the process of comparing the value of clinical services like drugs, devices, diagnostic and surgical procedures, medical services--is viewed as a means to vastly improve health care quality and ultimately improve value. Improving value will help stunt skyrocketing healthcare costs in recent years.

Comparative effectiveness research is widely supported by employers, health insurers, academics, and government officials. Some employers and a few cutting-edge health plans like Kaiser Permanente have been engaged in comparative effectiveness research for years.

However, the lack of dedicated resources and the absence of a concerted effort to share information have limited the potential of comparative effectiveness research within the existing construct. While there is general agreement about the essential role for government in conducting comparative effectiveness research, there is still debate about the extent to which the private sector should be engaged in administering comparative effectiveness research.

At the hearing witnesses discussed the benefits of comparative effectiveness research and what role the federal government can play.

Rising health care costs and variations in medical services have led to increasing calls for a federal role in research clarifying appropriate care.

Health policy experts across the political spectrum have identified information on the relative effectiveness of health care services as a public good that will not be produced in sufficient quality and quantity without government intervention. Various authorities have called for greater investments in comparative effectiveness research as critical to equitably managing ever rising health care costs. MedPAC, IOM and CBO have called for a national investment in comparative effectiveness information and have identified issues and options for the finance and governance of this activity.

Key Considerations

1. <u>What is Comparative Effectiveness Research?</u>

A MedPAC working paper describes "comparative effectiveness analysis" as comparing the value of alternate clinical services (drugs, devices, diagnostic and surgical procedures, medical services, no care). There are various forms of research

relevant to comparative effectiveness; these include NIH-style randomized studies done in academic settings, but more importantly, various forms of research on the effectiveness of tests and treatments in routine care.

2. Where is it currently done?

AHRQ, the lead federal agency for health services research, also carries a mandate through section 1013 of the MMA), and a related $15 million appropriation, to perform research with a focus on outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services. The provision has led to the creation of AHRQ's Effective Health Care Program, which has three components: 1) synthesizing existing studies into Comparative Effectiveness reports by evidence based practice centers, 2) developing evidence including research aimed at filling knowledge gaps about treatment effectiveness (DEcIDE centers), and 3) improving communication of complex scientific findings to a variety of audiences (Eisenberg Center).

The total of all appropriations to all federal agencies—the National Institutes of Health, the Veteran's Health Administration, the Department of Defense, the Centers for Medicare and Medicaid Services, the Food and Drug Administration, AHRQ, and the Centers for Disease Control and Prevention—for all health services research amounts to about $1.5 billion, only a small portion of which is devoted to clinical effectiveness research. Many policy makers are suggesting that the appropriate investment in CER should ultimately approach ~1% of expenditures on health care (ie around $20 billion). Current proposals suggest a ramp-up over the next 5 years to $1-3 billion annually

3. Who should pay for it?

Advocates note many risks to funding this activity thru annual appropriations, including possible politicization of the selection, production or dissemination of comparative effectiveness information. The Medicare Trust Fund is another source of funding, but participants in the Medicare program will not be the only users of the information. Therefore a variety of policy makers

have proposed additional support, such as from a levy on other payers for health care (eg employers, health insurers).

4. How should it be organized?

While much of the actual comparative effectiveness research will be conducted by faculty at universities and other research organizations, a high degree of central coordination is needed to meet the public need for useful and timely information. This coordinating function includes project priority setting; managing project timeliness; linkage of existing activities and resources; assured application of appropriate standards; and dissemination of authoritative findings. Furthermore this national effort will require development of improved study designs and research methodologies, of evidence standards, and of research skills and capacity.

Policy experts have proposed a variety of organizational models to coordinate this focused activity to enhance the Nation's capacity for comparative effectiveness research. The major options are "public funded entities," "private funded entities," or "public-private funded entities." AHRQ is the most logical current home of this initiative within the option of federal agencies.